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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,649	08/18/2003	Jack Chu	PA1515 (MEDT/0018)	5247

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EXAMINER	
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ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,649	CHU ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-42 and 46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-42 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments filed on 01/31/2008.

Drawings

The drawings were received on 03/12/2008. These drawings are acceptable.

Specification

The amendments to the Specification to include the descriptions of the drawings were received on 01/31/2008. These amendments are acceptable and will be entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-42, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims **1, 3-42, and 46-48** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant has argued and amended the claims to suggest that the shape of the stent provides the stent with its functional characteristics. The Examiner finds no support in the original documentation supporting the claim language "each turn of said helix having a diameter independent of the diameter of any other turn" (Claim 1 Line 5-6). One turn can not be expanded or contracted without some response from adjacent turns. The wire stent can not expand indefinitely. Without material being added or subtracted, there are limits to the expansion and contraction of the stent. One turn will take material from an adjacent turn as necessary. For example, a stent with three turns when expanded to a sufficient diameter will evolve into a stent with only two turns. Therefore, the Examiner considers the disclosure to lack a description to enable one of ordinary skill in the art to make or use the device and to include subject matter that was not sufficiently described in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1, 3-42, and 46-48** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Applicant has used the term "independent" in line 6 of claim 1. The Examiner can not determine the desired meaning of the word within the context of the claim. When in a fixed position, the turns may not depend on each other for size or shape, but as the stent's shape changes, the turns will be dependent on each other to some degree. Because the claim language suggests the stent is designed to change shape, the Examiner can not determine the exact meaning of the term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6, 7, 17-19, 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Jansen et al. (US 6,579,308).

Jansen discloses an intravascular treatment device, comprising: a contractable stent (2) locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing, has a middle portion and two end portionsand comprises at least one therapeutic agent (Column 2 Lines 49-50). The stent is helical, self-expanding, comprises nitinol, and the

stent is deployed by catheter to an aneurysm site (see figures 1-4 and disclosure). Claim 40 is a product-by-process claim and does not result in a different structure, thus not overcoming the prior art. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Once a product appearing to be substantially identical is found, the burden shifts to the Applicant to show an unobvious difference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Maass (US 4,553,545) or Segal (US 5,755,708) or Summers et al. (US 5,772,668) or Melzer et al. (US 6,280,385).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose double or triple helices. Maass, Segal, Summers, and

Melzer disclose stents with double helix configurations (see figures of references). Melzer in particular discloses multiple helix configurations. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's single helix to include double or triple helices. Such a modification would provide more coverage of the target site, increased surface area for the deliver of drugs, and other advantages as known in the art.

Claims 8, 9, 11, 12, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070.

Jansen discloses the invention substantially as claimed as stated above. Jansen further discloses the stent comprises a polymer (polyesters and polyurethane) as recited in claims 9 and 12. Jansen is silent on whether these polymers are biodegradable or not. Jansen does not explicitly disclose a therapeutic agent. Ragheb teaches a therapeutic agent (Col 19 Lines 22-27, Col 6 Lines 39-42 and Col 15 Line 56). Ragheb teaches that a variety of conventional materials can be employed as a base material for a stent, including biodegradable and non-biodegradable materials (Col 7 Lines 18-27). Jansen discloses the polymers for the stent as stated above. Jansen does not disclose the nature of the materials. However, because Ragheb teaches that conventional polymers are known to be either biodegradable or non-biodegradable, the Examiner considers it obvious to modify Jansen's polymers to be either biodegradable or non-biodegradable and to include drugs. Such a modification would in the biodegradable case allow the stent to degrade and thus not need to be removed. If the

stent is required to remain within the body indefinitely, a non-biodegradable polymer should be used. Placing drugs at the treatment site reduce inflammation, prevent clot formation, and may have additional benefits as known in the art.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 as applied to claim 8 above, and further in view of by Wright et al. (US 6,273,913).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the therapeutic agent being covalently linked to the polymer. Ragheb teaches covalently bonding heparin to the outermost surface of the stent (Col 8 Line 25). When this teaching is applied to Jansen, this heparin would be the therapeutic coating on the outside of the stent. The heparin then helps prevent clot formation. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Ragheb's covalent heparin. Such a modification would prevent clot formation. The Examiner also notes that Ragheb teaches the more general principle of using covalent bonds to link drugs to polymers. This teaching can be applied to Jansen when other drugs are to be administered. Basically, the concept is not limited to heparin. Wright teaches that drugs (specifically rapamycin) may be bound to a stent covalently via the Carmeda process (Col 5 Line 65 through Col 6 Line 10). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use covalent linking to bind the therapeutic agent to the polymer stent. Such a modification

provides a strong link to the polymer to allow for the release of the drug as desired based on the application.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Eisert (US 2005/0192664) and Hunter et al. (US 6,333,347).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the polymer being pH-sensitive and the polymer being temperature sensitive. Eisert teaches a pH sensitive polymer (Paragraph 64) that expands when contacted with a certain pH. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's pH-sensitive polymer. Such a modification would allow the stent to expand. Hunter '347 teaches that cellulose acetate phthalate is a pH sensitive polymer (Col 7 Lines 27-58). Therefore, it would have been obvious to use cellulose acetate phthalate as Eisert's pH-sensitive polymer.

Eisert teaches a temperature sensitive polymer (Paragraph 65) that takes on a new shape when heat is applied. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's temperature sensitive polymer. Such a modification would allow the stent to change shape upon application of heat. Hunter '347 teaches that pluronics F-127 is a temperature sensitive polymer (Col 8 Lines 41-65). Therefore, it would have been obvious to use pluronics F-127 as Eisert's temperature-sensitive polymer.

Claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Narciso, Jr. (US 5,419,760).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the specific type of therapeutic agent used. Narciso, Jr. teaches the application of aspirin to a stent to act as an anti-platelet/anti-thrombus drug (Col 5 Lines 55-68). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Narciso's aspirin. Such a modification would reduce clot formation.

Claims 28, 29, 31-39, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Hunter et al. (US 5,716,981).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose wherein the therapeutic agent is contained in microspheres. Hunter '981 teaches polymer microspheres made of polyvinyl alcohol (PVA) and size ranges of up to approximately 120 microns (figures 5-6, 9-10), release profiles of the therapeutic agent including about 1% to about 25% of the therapeutic agent released in the first 10 days (figure 15D), and the coating being a spray from microspheres (17 Lines 7-67 through Col 18 Lines 1-7). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Jansen's stent to include Hunter's microspheres and release profile. Such a modification would allow for a controlled release of a desired amount to the target site.

Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 further in view of Vallana et al. (US 2003/0028242) and Hunter '981.

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose wherein the therapeutic is applied as a coating the coating further comprising a polymer, the nature of the application of the coating, a second coating, two therapeutic coatings, the polymer coating being biodegradable, and wherein the coating is time-released. Ragheb teaches the therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62); the coating being applied as a film (Col 18 Line 2); a second coating deposed over the therapeutic coating (Fig. 2 Item 20); at least two therapeutic coatings, wherein each therapeutic coating is separated by a second coating (Fig. 2 Items 18, 22, and 24); the coating being a biodegradable coating (Col 9 Lines 20-67); the polymer being heparin (Col 9 Line 23); the coating being a time release coating (Col 10 Lines 30-35). Multiple coating allow for multiple drugs to be released or the same drug to be released with different time-release characteristics. Ragheb does not disclose the therapeutic coating further comprising a polymer. Vallana teaches that polymers are used as carriers for therapeutic coatings (Paragraph 65). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Ragheb's coating inlcuding Vallana's polymer. Such a modification provides the advantage of additional control over the release

characteristics of the drug. Furthermore, the polymer carrier coating of Vallana is considered a time-release coating being that the therapeutic agent is released over time. It is also noted that Hunter '981 discloses a polymer carrier as stated above. The combination of Hunter '981, Ragheb, and Jansen would apply in the same manner as the combination of Ragheb, Vallana, and Jansen.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,658).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the method including a stent graft, and wherein the therapeutic agent is inactive until activated. Clouse teaches first inserting a stent to an aneurysm site and then inserting a graft (Col 3 Line 46 through Col 4 Line 13). This shows that it is known to deliver a stent before delivering the graft with the stent between the graft and the aneurysm. The Clouse reference discloses the graft traversing the aneurysm in order to prevent pressure on the aneurysm. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's method to include Clouse's stent graft. Such a modification would prevent pressure on the aneurysm from blood flow. Obviously, Jansen's stent would need to be inserted before Clouse's. If not, Jansen's stent would not be able to be located so that it engages the aneurysm. Jansen's stent would act in a similar manner to vaso-occlusive coils and provide drug treatment and other advantages to the aneurysm site.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,658) as applied to claim 46 above, and further in view of Falotico et al. (US 2003/0060877).

Jansen and Clouse disclose the invention substantially as claimed as stated above. They do not explicitly disclose the method wherein the therapeutic agent is inactive until activated. Falotico teaches a therapeutic agent being inactive until it comes in contact with an activating agent (Paragraph 142). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's agent to include the therapeutic agent and the activation characteristic of Falotico. Such a modification would allow for additional measure of time release.

Response to Arguments

Applicant's arguments filed 01/31/2008 have been fully considered but they are not persuasive.

The Applicant has argued that the function of the stent is a product of its shape and not the material it is made from. The shape of the stent is helical. When placed in an aneurysm, it expands to fill the aneurysm. As the site contracts, so does the stent. The basic shape of the stent is a simple helix. The enlarged middle diameter portion is a function of the stent's placement. From the general description of the device, it is apparent that the stent will take the shape of the vessel wall. There is no suggestion

that it is preformed with an enlarged middle portion. This is why the Examiner considers the amendment to include new matter.

The prior art Jansen discloses a helical wire stent made from the same material as the Applicant's device. As stated in the previous action, there is no reason to believe that the prior art will perform differently from the claimed invention. The Applicant has abandoned the argument that the stent's material differentiates it from the prior art. The Examiner considers that matter closed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731